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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,409

06/25/2003

Samuel M. Shaolian

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EXAMINER

PRIDDY, MICHAEL B

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

09/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/606,409

Applicant(s)

SHAOLIAN ET AL.

Examiner

Michael B. Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2007 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant (US 5,030,201). Palestrant teaches a device capable of enucleation comprising: a proximal end; a distal end comprising a cutting cap comprising a plurality of elastically deformable blades 36, 38, 40, etc.; and a flexible shaft 26 between the proximal end and the cutting cap; where the plurality of elastically deformable blades 36, etc. can cut material in a space when the blades are not deformed, after accessing the space through a passage while the blades are deformed; and where the passage

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has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material; wherein an axial guidewire lumen (surrounding wire 32) extends between the proximal end and the distal end.

Claims 1, 4-6, 11, 14, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ratcliff et al. (U.S. 5,709,697). Ratcliff et al. teach a method of cutting material in a space, comprising: providing device having a proximal end, a distal end comprising a cutting cap comprising a plurality of deformable blades 160 formed of shape memory alloy (line 45 of column 4); and a shaft 112 between the proximal end and the cutting cap, where the plurality of elastically deformable blades 160 can cut material in a space when the blades 160 are not deformed, after accessing the space through a passage while the blades are deformed; and where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades 160 while the blades 160 are cutting the material; accessing the space with the device (line 36 of column 5); actuating the device, thereby effecting cutting of the material (line 45 of column 5 through line 17 of column 6); deforming the blades before actuation the device, and accessing the space through a passage while the blades are deformed; where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material (lines 46-65 of column 5); retracting the cutting device after cutting material (lines 23-29 of column 6).

Concerning the limitations of claim 6 requiring the passage be curved, it is noted that Ratcliff et al. indicate the device, in use, can be inserted through a trocar cannula (line 38 of column 5). Trocar cannulas are known to have round (curved) cross-sections.

Claims 1, 4, 8, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Groshong (U.S. 5,178,625). Groshong teaches a method of cutting material in a space, comprising: providing device having a proximal end, a distal end comprising a cutting cap comprising a plurality of deformable blades 34/35; and a shaft 14 between the proximal end and the cutting cap, where the plurality of elastically deformable blades can cut material in a space when the blades are not deformed, after accessing the space through a passage while the blades are deformed; and where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material.

Groshong teaches *creating* a passage to access the space; *deforming* the blades to fit through the passage; *advancing* the device through the passage until the cutting cap passes into the space, thereby allowing the blades to expand to their undeformed shape; *actuating* the device thereby effecting cutting of the material; where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material; wherein advancing the cutting device through the passage comprises *advancing* the cutting device over a guide wire (lines 15-62 of column 11).

Claim Rejections - 35 USC § 103

Claims 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratcliff et al. as applied to claims 4 and 11 above, and further in view of the following. Ratcliff et al. teaches all of the limitations of the present invention except advancing the device in the space to cut additional material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Ratcliff et al. a second time (advancing the cutting device in the space to cut additional material), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 1, 4, 9, 11, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Middleton et al. (US 6,746,451). Middleton et al. teach *providing* a device 100 having a proximal end, a distal end comprising a cutting cap comprising an elastically deformable blade 120; and a shaft 110 between the proximal end and the cutting cap, where the plurality of elastically deformable blade 120 can cut material in a space when the blade 120 are not deformed, after accessing the space through a passage while the blade 120 are deformed; and where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blade 120 while the blade 120 are cutting the material; *creating* a passage to access the space (lines 55-59 of column 3); *deforming* the blades to fit through the passage (lines 60-65

of column 3 and Fig. 13A); *advancing* the device through the passage until the cutting cap passes into the space, thereby allowing the blades to expand to their undeformed shape (lines 60-65 of column 3 and Fig. 13A); *actuating* the device thereby effecting cutting of the material (lines 60-65 of column 3 and Fig. 13A); where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the.

Hence the embodiment of Middleton et al. shown in Figs. 2A, 2B, 3A-C & 13A-B teaches all of the limitations of the present invention except a *plurality* of deformable blades. In Figures 7A & B Middleton et al. teach a device having two elastically deformable blades 520. It would have obvious to one having ordinary skill in the art at the time of the present invention to use the embodiment of Figures 7A & B in the method depicted in Figures 13A&B to provide for a smoother, more-balanced cutting path.

Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Middleton et al. as applied to claims 4 and 11 above, and further in view of Reiley et al. (U.S. 6,248,110 B1). Middleton et al. teach all of the limitations of the present invention except advancing the device through a transpedicular access passage in a vertebra.

Scribner et al. (U.S. 5,792,015) teach treating diseased vertebrae via a transpedicular approach (Figs. 5, 6, 7 & 8) and indicated in a transpedicular approach is typical (lines 58-60 of column 6). It would have been obvious to one of ordinary skill in

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the art at the time of the present invention to use a transpedicular approach as taught by Scribner et al. with the tissue removal method of Middleton et al. as one of a finite number of known and predictable solutions for accessing the intervertebral space.

Response to Arguments

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

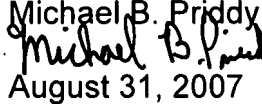
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is 571-272-2243. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael B. Priddy

August 31, 2007


EDUARDO C. ROBERT
SOPH PATENT EXAMINER